

SPECIAL REPORT

Trials & Tribulation

Advocating for the Value of Clinical Trials

By Mary Mashburn

Fran Visco is the National Breast Cancer Coalition's most visible face, and it's a game face, the kind you put on before you walk out on the field ready to take some hits and hand some out. Sure, she projects warmth and charm, but there's just no mistaking the reinforced steel behind the large brown eyes.

Visco and her team of like-minded advocates are players in the fight to eradicate breast cancer. They want the research to move forward--fast--but with purpose. And one way to make that happen, they believe, is to emphasize the value of clinical trials to fellow breast cancer activists.

Fran Visco, National Breast Cancer Coalition president



"We want to make certain our community is educated about the importance of clinical trials, understands how to analyze a clinical trial, and is involved in getting clinical trials to move forward, because we want the answers to how best to treat and prevent this disease," says Visco, sitting in the coalition's office just blocks from the White House in Washington, D.C. Currently, less than 3 percent of adult cancer patients in the U.S. participate in clinical trials, the "gold standard" for determining whether a treatment will be beneficial.

The NBCC, formed in 1991, encompasses 600 organizations and more than 60,000 individual members, many of them women who have or have had breast cancer. The coalition's goals are to improve the quality of and increase funding for breast cancer research, to expand access to high-quality health care and clinical trials, and to expand the influence of breast cancer advocates, from how research money is spent to how clinical trials are designed.

Often, the issue is not just how a particular trial is conducted, but whether precious research dollars should even be allocated. "We feel there are studies and trials out there that are not really asking a question that anybody cares about, that they're looking at minimal, incremental changes," says Visco. "If we are going to allocate resources, resources being people's lives and dollars and the focus of the scientific community, is it going to be on minimizing hair loss [a side effect of chemotherapy] or is it going to be on how do we prevent breast cancer?"

The NBCC can point to several successes that have changed the

landscape of research and treatment. Among them: Coalition members lobbied for increased federal funding, and got a research program within the Department of Defense; total dollars allocated to it since 1991 have reached \$1 billion. Concerned that a law to provide free screening for breast and cervical cancer had no provision for treatment, the NBCC worked to pass the Breast Cancer and Cervical Treatment Act, which offers a federal incentive to states to provide Medicaid coverage for low-income women diagnosed with cancer. Currently, Visco's powerful lobbying skills are focused on getting insurance companies to pay patient costs for clinical trials. "People aren't going to go into clinical trials if it's going to cost them, and we need them to go into trials, because we need to get the answers," she says.

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The coalition is adamant that advocates should play a role in the design, review, and implementation of trials. "We believe it's incredibly important to have the perspective and participation of trained advocates at every level, not just as subjects for the research," says Visco. "We want to be collaborators with the scientists." The NBCC has a formidable resume: breast cancer advocates participating in the peer review process for research at the Department of Defense; and key research partnerships with industry, beginning in 1996 with the biotech giant Genentech on Phase III clinical trials for Herceptin, a biologic drug for patients with metastatic breast cancer.

Breast cancer advocates served on the steering committee for the Genentech trial, developed materials for outreach, sat on the data safety monitoring board, and accompanied company representatives to meetings with the FDA. The coalition also used its extensive grassroots network to help enroll women in the trial, thus speeding up research. "The company has said a number of times that that drug was on the market two years earlier than it would have been without our participation," Visco says.

The emphasis on collaboration comes from the coalition's belief that breast cancer advocates bring a unique perspective. Visco's assessment is stark and to the point: "The only thing we want to see is breast cancer ended. All the scientists, they want that too. But they have pressures, conflicts of interests: getting published in the *New England Journal of Medicine*, the bonuses involved in enrolling individuals in trials, tenure, maintaining a lab. I don't mean to say any of this is going to cause a scientist to make a decision that she or he wouldn't otherwise, but the perception may be there. With us, there's no hidden agenda."

Visco doesn't underplay the difficulty of advocates being accepted by researchers. "I think the most common misperception is that we don't have anything to offer—it may be because they think we're yelling and screaming, or we don't understand the issues, or they think we're only there to talk about our own disease."

In fact, the NBCC is zealous about educating advocates. Through a series of workshops called Project Lead, the coalition has trained about 800 people in the basic science and epidemiology of disease, as well as the intricacies of clinical trials. Project Lead graduates use their training in their own communities, helping others to better evaluate treatment options,

lobbying for increased access to care, or serving as lay people on review boards for clinical trials. Last summer, the NBCC invited scientists, clinicians, ethicists, and epidemiologists—including several from Hopkins—to provide more in-depth clinical trials training for a small group of advocates.

Although Visco is pleased at the progress the NBCC has made in gaining a seat at the table, she knows there's a long way to go. "Patient advocacy is trendy right now, but too often the medical and research community looks for the advocate who will agree. We are not those advocates. We are advocates who have the ability and the courage to disagree when we think it's appropriate.

"If your goal is our goal--to find the answers to breast cancer as soon as possible--then we're the advocates you want to work with. It's not easy to work with us, but I don't find it's easy to work with the scientists either. We're willing to put up with them, they should be willing to put up with us," Visco says, smiling a bit, but very, very serious.

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